K121502

SYNTHES®

AUG 2 3 2012

5 510(k) Summary

Date Prepared May 10, 2012

Submitter Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
United States of America

Contact Alan T. Haley
haley.alan@synthes.com
(484) 356-9763

Device Name Synthes Curvilinear Distraction System
(Mandibular distractor)

Classification Name Class II, 21 CFR 872.4760, Product Code MQN

Predicate Devices

- Synthes Curvilinear Distraction System (K080153)
- Synthes Craniomaxillofacial (CMF) Distraction System (K060138)
- OsteoMed Intraoral Mandibular Distraction System (K013618)
- OsteoMed Pediatric Intraoral Mandibular Distraction System (K043434)

Indications for Use

The Synthes Curvilinear Distraction System is intended for use as a bone stabilizer and lengthening (and/or transport) device. The Synthes Curvilinear Distraction System is indicated for correction of congenital deficiencies or posttraumatic defects of the mandibular body and ramus where gradual bone distraction is required.

The 2.0 mm Curvilinear Distractor is intended for use in adult and pediatric patients more than 1 year old.

The 1.3 mm Curvilinear Distractor is intended for use in pediatric patients 4 years of age and younger.

The Synthes Curvilinear Distraction System is intended for single use only.

Device Description

The Synthes Curvilinear Distraction System is a family of internal distraction osteogenesis devices that gradually advance the mandible along a specific trajectory of distraction. The system features various curved and straight distractors in two sizes; the 1.3mm Curvilinear Distractor and the 2.0mm Curvilinear Distractor. The distractors accept extension arms which move the point of activation to a location that is easily accessible with the activation instrument. Synthes Curvilinear Distraction System devices are manufactured from titanium alloy and chromium cobalt alloy. Devices are supplied non-sterile and must be sterilized prior to use.

Device Description (continued)

The distractor features a worm gear that is activated to move the distractor along a curved or straight track. The distractor consists of three main components:

Track	The track has grooves in 1 mm intervals which may be placed in a straight line (for a straight distractor) or on a centerline radius (for a curved distractor). The track is manufactured with a crimp that serves as a functional stop to prevent the distractor from separating at the end of the track. The track is 35mm in length and can be cut to the desired length for each particular patient by the surgeon. After cutting, the track is crimped to re-establish the functional stop to prevent separation.
Worm gear activation assembly	The worm activation assembly consists of the worm gear and a universal joint activation hex. The universal joint is capable of + or - 35° of angulation. The worm gear has a 1 mm pitch and rides along the grooves cut into the track. The worm gear activation assembly is inserted into the housing and the track with grooves is threaded through a slot in the side of the housing.
Housing	The housing includes a tab that lays on the activation assembly to prevent the distractor from reversing due to micromotion.

Comparison to Predicate Devices

Indications

The Indications statement for the proposed device is similar to the statements of all of the predicate devices in that they are to be used for distraction osteogenesis of the mandible. Although the wording for each specific Indications statement varies, they are all cleared for the same clinical application - bone stabilization and lengthening (and/or transport) of the mandible where gradual bone distraction is required.

Both the proposed device and the OsteoMed Pediatric Intraoral Mandibular Distraction System (K043434) predicate are intended for use in patients under 4 years of age. The proposed device is similar to the Synthes Craniomaxillofacial (CMF) Distraction System (K060138) predicate which includes devices for patients under the age of 12 months as well as devices for patients over 1 year of age.

The differences in the Indications statement for the proposed device in comparison to the predicates do not constitute a new intended use.

Comparison to Predicate Devices (continued)

Technological Similarities

- The proposed device and the predicate devices consist of mesh footplates designed to attach to the mandible with bone screws.
- The proposed device and the predicate devices include an advancement mechanism designed to move the mobilized segment(s) of the mandible to generate new bone as part of the distraction osteogenesis treatment process.
- The proposed device uses the same worm drive mechanism as Synthes Curvilinear Distraction System (K080153) predicate.
- The proposed device and the predicate devices are manufactured from titanium/titanium alloys and chromium cobalt, each of which meets the requirements of its respective ASTM standard. Titanium and titanium alloys have a long, established history of use as a surgical implant material.

Technological Differences

- The advancement mechanism for the proposed device is a worm drive, whereas the Synthes Craniomaxillofacial (CMF) Distraction System (K060138) the OsteoMed Intraoral Mandibular Distraction System (K013618), and OsteoMed Pediatric Intraoral Mandibular Distraction System (K043434) predicates employ a center lead screw.

Non-clinical performance data

Mechanical testing was used to demonstrate that any differences, where they do exist, do not negatively impact safety and effectiveness.

Four point bend testing was performed to demonstrate that the proposed 1.3 mm Curvilinear Distractor can withstand forces applied to it from mastication and can resist permanent deformation within the range of the predicate devices.

Torque-force testing was also conducted to show that the proposed 1.3 mm Curvilinear Distractor can generate sufficient force to overcome the anatomical resistance to distraction (soft tissue resistance, callus stretching, etc.) by over three times the acceptance criterion.

Clinical performance data

Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence

The proposed device has the same intended use as the predicate devices. The mechanical testing included in this submission demonstrates that the slight differences in technological characteristics do not raise any new questions of safety and effectiveness and that the proposed device is at least as safe and effective as the predicates. The information submitted supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes Incorporated
Mr. Alan T. Haley
CMF Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

AUG 2 3 2012

Re: K121502
Trade/Device Name: Synthes Curvilinear Distraction System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: August 10, 2012
Received: August 13, 2012

Dear Mr. Haley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

4 Indications for Use Statement

510(k) Number (if known): K121502

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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